

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

DMB

File No.	4-11-00
Revision Date	4-12-00
Certifier	SN Reese

**Food and Drug Administration**

**Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Cardiovascular and Renal Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on May 1, 2000, from 8:30 a.m. to 5:30 p.m., and on May 2, 2000, from 9 a.m. to 5:30 p.m.

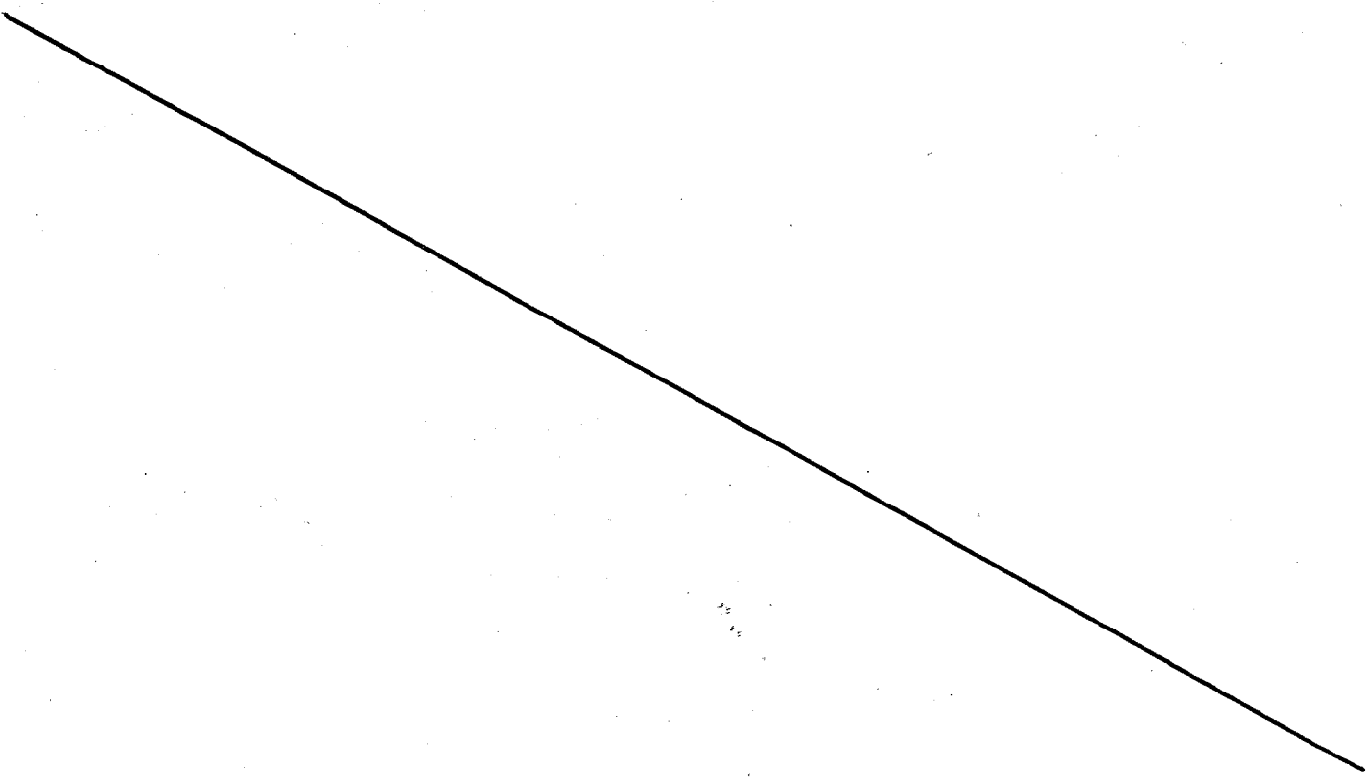
*Location:* National Institutes of Health, 9000 Rockville Pike, Bldg. 10, Clinical Center, Jack Masur Auditorium, Bethesda, MD.

*Contact Person:* Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, Woodmont II Bldg., 1451 Rockville Pike, Rockville, MD 20752, 419-259-6211, or John M. Treacy (HFD-21), 301-827-7001 or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On May 1, 2000, the committee will discuss new drug applications (NDA) 21-188, Vanlev® (omapatrilat) Bristol Myers Squibb to be indicated for hypertension, and NDA 19-901, Altace® (ramipril) Capsules, King Pharmaceuticals, Inc., to be indicated for significant reduction of mortality, myocardial infarction, stroke, revascularization procedures, and heart failure in high risk patients. On May 2, 2000, the committee will discuss NDA 20-807/S-004, Refludan®

[lepirudin(-DNA) for injection] Aventis Pharmaceuticals, Inc., to be indicated for anticoagulation in adult patients with acute coronary syndromes (unstable angina and acute myocardial infarction without ST segment elevations on electrocardiogram (EKG).

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 24, 2000. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on May 1, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 24, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C., app.

2).

Dated:

April 4, 2000  
April 4, 2000

Linda A. Suydam

Linda A. Suydam  
Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

Suzette N. Reese